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EXAMINER

AKHAVANNIK, HUSSEIN

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2621

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15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/531,262

Applicant(s)

ZEYLIKOVICH ET AL.

Examiner

Hussein Akhavannik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

1. The amendment to claim 14 overcomes the objection cited by the Examiner in paragraph 2 of the previous office action (now Paper No. 12).
2. The amendment to claim 3 overcomes the 35 U.S.C. 112, second paragraph rejection cited by the Examiner in paragraph 5 of the previous office action (now Paper No. 12).

***Response to Arguments***

3. Applicant's arguments with respect to claims 1, 3, 12, 18-19, and 23 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al (U.S. Patent No. 5,799,656) in view of Essenpreis et al (U.S. Patent No. 5,713,352), and further in view of Ning (U.S. Patent No. 6,480,565).

Referring to claim 1,

- i. Illuminating the host medium at a plurality of different positions is illustrated by Alfano et al in figure 1 by the mode locked laser 13 and the calcium sample (corresponding to the host medium). The entire sample is illuminated and further detected to create shadow images as illustrated by Alfano et al in figures 3(a) to 3(d).

- ii. Detecting signals following propagation through the host medium and the abnormality within the host medium is illustrated by Alfano et al in figure 1 by the CCD camera 35.
- iii. Creating a shadow image based upon the detected signals in which the abnormality is depicted as a suspicious region is illustrated by Alfano et al by the shadow images in which the abnormalities are depicted in figures 3(a) to 3(d). Alfano et al explain the depicted calcifications in column 7, lines 4-19 and further explain in column 9, lines 23-26 that calcifications may be detected in order to identify malignant and benign tissues.
- iv. Illuminating at least that portion of the host medium that contains the suspicious region with frequency-swept modulated signals, following the creation of a shadow image is not explicitly explained by Alfano et al. Essenpreis et al explain modulating a light source through a range of 50 MHz to 1000 MHz in column 5, lines 26-40. Essenpreis et al explain that sweeping through the frequency range enables a system to describe the change in intensity of the transmitted light due to interaction with a biological matrix (such as breast tissue) in column 1, line 53 to column 2, line 4. By modulating the light source Alfano et al through a range of predetermined frequencies, the detection of malignant and benign breast tissue would be improved in the system of Alfano et al, which would result in more accurate breast cancer detection. Furthermore, Ning explicitly explains performing a detailed interrogation (as performed by Essenpreis et al) of specific regions within a lesion, such as a microcalcification detected by Alfano et al, to enable more accurate characterization of the breast lesion in column 6, lines 3-9.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to illuminate at least that portion of the host medium that contains the suspicious region, as determined by Alfano et al, with frequency-swept modulated signals, as explained by Essenpreis et al, because the suspicious region will be more accurately characterized, as suggested by Ning.

v. Detecting the frequency-swept modulated signals following propagation through at least that portion of the host medium that contains the suspicious region is illustrated by system of Alfano et al, Essenpreis et al, and Ning. Essenpreis et al illustrate the detectors 15A and 15B in figure 2.

vi. Characterizing the abnormality based upon the detected frequency-swept modulated signals is explained by system of Alfano et al, Essenpreis et al, and Ning. Alfano et al explain characterizing the dark shadow regions of figures 3(a) to 3(d) as calcium particles in column 7, lines 16-17. Alfano et al also explain identifying malignant and benign (corresponding to characterizing) tissues from calcification and normal regions in column 9, lines 23-26. Essenpreis et al explain determining the interaction of a biological matrix with frequency-swept modulated signals in column 1, line 53 to column 2, line 4. Finally, Ning explains determining a more accurate representation of breast lesions in column 6, lines 3-9.

Referring to claim 2, the initial illumination step comprising illuminating the host medium at a plurality of different positions with signals modulated at a frequency selected from a range of frequencies is explained by Alfano et al in column 6, lines 38-48, wherein the mode-locked laser of Alfano et al emits laser pulses with a duration time of 8 ps.

Referring to claim 3, during the second illumination step, the signals being frequency-swept modulated across a larger range of frequencies than the range of frequencies from which the modulation frequency of the signal that initially illuminates the host medium corresponds to claim 1i-iv. The initial range of frequency swept illumination in the system of Alfano et al, Essenpreis et al, and Ning is 1, corresponding to a duration time of 8 ps as explained in column 6, lines 38-48. The second range of frequency swept illumination in the system of Alfano et al, Essenpreis et al, and Ning is 950 MHz (1000 MHz - 50 MHz) as explained by Essenpreis et al in column 5, lines 26-40.

6. Claims 4-5, 7, 10-12, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al in view of Essenpreis et al and Ning, and further in view of Nelson et al (U.S. Patent No. 5,999,836).

Referring to claim 4, the illumination step comprising illuminating the host medium with signals having at least two different wavelengths is not explicitly explained by Alfano et al or Essenpreis et al or Ning. However, Nelson et al illustrate beams having wavelengths  $\lambda_1$  and  $\lambda_2$  in figure 17. Nelson et al explain that the use of multiple beams enhances the capability of an imaging system to localize the presence of materials that can be detected using emission Florescence. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to illuminate the host medium with signals having at least two different wavelengths as suggested by Nelson et al in the system of Alfano et al, Essenpreis et al, and Ning because the imaging system would be enhanced.

Referring to claim 5, the initial detecting step comprising detecting at least an amplitude of the signals following propagation through the host medium and the abnormality within the

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host medium is illustrated by Alfano et al figure 1 by the CCD camera 35. The CCD camera determines the intensity of light (photons) passing through the host medium.

Referring to claim 7, illuminating at least that portion of the host medium that contains the suspicious region with signals having at least two different wavelengths is not explicitly explained by Alfano et al or Essenpreis et al or Ning. However, Nelson et al illustrate beams having wavelengths  $\lambda_1$  and  $\lambda_2$  in figure 17. Nelson et al explain that the use of multiple beams enhances the capability of an imaging system to localize the presence of materials that can be detected using emission Florescence. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to illuminate at least that portion of the host medium that contains the suspicious region with signals having at least two different wavelengths as suggested by Nelson et al in the system of Alfano et al, Essenpreis et al, and Ning because the imaging system would be enhanced.

Referring to claim 10, the second illuminating step comprising positioning a light source at a position offset from the suspicious region and the second detecting step comprises moving the detector along a linear path displaced from the suspicious region is not explicitly explained by Alfano et al or Essenpreis et al or Ning. However, Nelson et al illustrate in figure 5 that the two source/detector combinations can be positioned anywhere along the two linear paths illustrated by the dotted arrows. The combinations can be linearly positioned at the suspected lesion during the frequency-swept illumination of the lesions corresponding to claim 1iv. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to position a light source at a position offset from the suspicious region and move the detector along a linear path displaced from the suspicious region as suggested by Nelson et al in

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the system of Alfano et al, Essenpreis et al, and Ning because the entire suspicious region would be imaged resulting in a more accurate representation of the suspicious region.

Referring to claim 11, the second illuminating step comprising positioning a light source at a position offset from the suspicious region and the second detecting step comprises moving the detector through a plurality of positions including at least one position aligned with the suspicious region is not explicitly explained by Alfano et al or Essenpreis et al or Ning.

However, Nelson et al illustrate in figure 5 that the two source/detector combinations can be positioned anywhere along the two linear paths illustrated by the dotted arrows. By moving through a plurality of positions to scan the suspect lesion, each source/detector combination would move through a plurality of positions, including at least one position aligned with a suspect region. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to position a light source at a position offset from the suspicious region and move the detector through a plurality of positions including at least one position aligned with the suspicious region as suggested by Nelson et al in the system of Alfano et al, Essenpreis et al, and Ning because the entire suspicious region would be imaged resulting in a more accurate representation of the suspicious region.

Referring to claim 12,

i. Positioning a light source and a detector on opposite sides of the host medium in an offset relation is not explicitly explained by Alfano et al or Essenpreis et al or Ning.

However, Nelson et al illustrate in figure 17 that each of the three emitters and detectors are positioned on opposite sides of the host medium in an offset relation.

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ii. Moving the light source and the detector in tandem such that the offset relation is maintained is not explicitly explained by Alfano et al or Essenpreis et al or Ning.

However, Nelson et al explain in column 7, lines 27-30 that the light source and detector are moved in a raster scan format, wherein the light source and detector are moved in tandem across the breast in order to completely image the breast. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to position a light source and a detector on opposite sides of the host medium in an offset relation and move the light source and the detector in tandem such that the offset relation is maintained as suggested by Nelson et al in the system of Alfano et al, Essenpreis et al, and Ning because the entire suspicious region would be imaged resulting in a more accurate representation of the suspicious region.

Referring to claim 16, the host medium being a breast and compressing the breast between a pair of plates prior to the initial illumination step is not explicitly explained by Alfano et al or Essenpreis et al or Ning. Alfano et al do explain the host medium being a breast in column 9, lines 55-59. However, Nelson et al illustrate in figure 8a that a breast (104) is compressed between two plates (102a and 102b). Nelson et al explain that breast compression is desirable because the contribution of scattered signals would be diminished and because the tissue would exhibit uniform thickness in column 3, lines 58-63. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to compress a breast between a pair of plates prior to the initial illumination step as suggested by Nelson et al in the system of Alfano et al, Essenpreis et al, and Ning because the contribution of scattered signals would be diminished and because the tissue would exhibit uniform thickness.

Referring to claim 17, the host medium being a breast and applying oil to the breast prior to the initial illumination step is not explicitly explained by Alfano et al or Essenpreis et al or Ning. Alfano et al do explain the host medium being a breast in column 9, lines 55-59. However, Nelson et al explain covering the breast in a gel in column 17, lines 33-44. Nelson et al explain that the gel can help dissipate local buildup of heat and lubricate the breast. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply oil to the breast prior to the initial illumination step, as suggested by Nelson et al in the system of Alfano et al, Essenpreis et al, and Ning because the gel can help dissipate local buildup of heat and lubricate the breast.

7. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al in view of Essenpreis et al, Ning, and Nelson et al, and further in view of Tsuchiya (U.S. Patent No. 5,983,121).

Referring to claim 6, forming a ratio of the amplitude of the signals detected during the initial detecting step at each of the different wavelengths is not explicitly explained by Alfano et al or Essenpreis et al or Ning or Nelson et al. However, Tsuchiya explain calculating the amplitude of signals detected at two separate wavelengths in column 14, lines 37-53. The ratio of the amplitudes is detected in order to calculate the specific absorptive constituent at every scanned location. By determining the absorptive constituent, malignant regions in the breast tissue can be more accurately determined, due to their differing absorptive properties. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a ratio of the amplitude of the signals detected at different wavelengths, as suggested by

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Tsuchiya in the system of Alfano et al, Essenpreis et al, Ning, and Nelson et al because the regions in the breast tissue (host medium) will be characterized more accurately.

Referring to claims 8, determining a P-criteria for at least one of the plurality of positions within at least that portion of the host medium that contains the suspicious region, wherein the P-criteria is at least partially based upon coefficients of absorptivity for signals having the different wavelengths at the respective position corresponds to claim 6. The ratio of the amplitudes of the photons corresponds to the absorptivity of the signals, since the photons from the source pass through the breast tissue in the transillumination scanning of Tsuchiya. Therefore, the ratio of Tsuchiya corresponds to the claimed P-criteria.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al in view of Essenpreis et al and Ning, and further in view of Tsuchiya.

Referring to claim 9, determining an  $S_{\text{var}}$ -criteria for at least one of the plurality of positions within at least that portion of the host medium that contains the suspicious region, wherein the  $S_{\text{var}}$ -criteria is at least partially based upon a variation in percent concentration of oxygenated hemoglobin between the abnormality and the host medium and a variation in total hemoglobin concentration between the abnormality and the host medium at the respective position is not explicitly explained by Alfano et al or Essenpreis et al or Ning. However, Tsuchiya explain determining the concentration of oxygenated hemoglobin inside a host medium, including the suspicious regions, in column 22, lines 11-28. It is well known that different types of tissue contain different concentrations of oxygenated hemoglobin. Thus, by determining the concentration of oxygenated hemoglobin, a suspected mass can be better identified from the normal tissue. Therefore, it would have been obvious to one of ordinary skill

in the art at the time the invention was made to determine the variation of oxygenated hemoglobin between normal tissue and a suspicious mass, as suggested by Tsuchiya in the system of Alfano et al, Essenpreis et al, and Ning because the suspicious mass will be more accurately characterized, leading to more accurate cancer detection.

9. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al in view of Essenpreis et al and Ning, and further in view of Nelson et al and Chance (U.S. Patent No. 5,555,885).

Referring to claim 13,

- i. Illuminating a portion of the host medium at a plurality of different positions displaced from the suspicious region with signals having at least two different wavelengths corresponds to claim 4.
  - ii. Detecting the signals following propagation through the host medium corresponds to claim 5.
  - iii. Determining a reference scattering coefficient and a reference absorption coefficient for the host medium based upon the detected signals is not explicitly explained by Alfano et al or Essenpreis et al or Ning or Nelson et al. However, Chance explains using the scattering coefficient and the absorption coefficient to characterize the examined breast tissue in the abstract. By determining the scattering coefficient and the reference absorption coefficient, malignant regions in the breast tissue can be more accurately determined, due to their differing absorptive and scattering properties.
- Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the scattering coefficient and the reference absorption

coefficient for a host medium, as explained by Chance in the system of Alfano et al, Essenpreis et al, Ning, and Nelson et al because regions in the scanned breast tissue would be characterized more accurately.

Referring to claim 14, determining an absorption coefficient and a size of the abnormality based on setting a scattering coefficient of the abnormality equal to the reference scattering coefficient and further based upon the frequency-swept modulated signals that are detected following propagation through at least that portion of the host medium that contains the suspicious region is not explicitly explained by Alfano et al or Essenpreis et al or Ning or Nelson et al. However, Chance explains determining the absorption coefficient of an abnormality, corresponding to claim 13. Chance further explains determining the size of an abnormality in column 3, lines 9-10. Determining the size of an abnormality would allow the mammography system of Alfano et al, Essenpreis et al, Ning, and Nelson et al to better characterize a suspected mass. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the absorption coefficient and a size of the abnormality, as explained by Chance, in the system of Alfano et al, Essenpreis et al, Ning, and Nelson et al because the abnormal regions will be more accurately characterized.

Referring to claim 15, determining a location of the abnormality within the host medium following the second detecting step is illustrated by Alfano et al in figures 3(a) and 3(c). The locations of the abnormalities are illustrated by Alfano et al.

10. Claims 18-19, 22, 24-25, 28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al in view of Essenpreis et al and Alfano et al, further in view of Ning.

Referring to claim 18,

- i. A light source for illuminating the host medium at a plurality of different positions is illustrated by Nelson et al in figure 1b. The two light sources, source 1 and source 2, illuminate a host medium and are moved in a scan direction (arrow labeled “scan direction”) in order to illuminate a plurality of different positions.
- ii. A modulator for applying frequency-swept modulation to the signals generated by the light source prior to illuminating the host medium is not explicitly explained by Nelson et al. . Nelson et al do explain illuminating a breast, including any suspicious regions, using multiple light sources that may range from continuous to rapidly pulsed in column 17, lines 45-61. A modulator would be inherently required to rapidly pulse a light source in the system of Nelson et al. However, Nelson et al do not explicitly explain the light sources sweeping through different pulsing frequencies. Essenpreis et al do explain modulating the light source through a range from 50 MHz to 1000 MHz in column 5, lines 26-40. Essenpreis et al explain that sweeping through a frequency range enables a system to describe the change in intensity of the transmitted light due to interaction with a biological matrix (such as breast tissue) in column 1, line 53 to column 2, line 4. By modulating the light sources of Nelson et al through a range of predetermined frequencies by using a modulator, the detection of breast tissue would be improved in the system of Nelson et al, which would result in more accurate breast cancer detection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a modulator to apply frequency-swept modulation to the signals generated by a light source prior to illuminating the host

medium, as explained by Essenpreis et al, in the system of Nelson et al because the suspicious regions in breast tissue would be characterized more accurately.

iii. A detector for detecting signals following propagation through the host medium and the abnormality within the host medium is illustrated by Nelson et al in figures 2a to 2c by the photon detectors.

iv. A display for presenting a shadow image based upon the detected signals in which the abnormality is depicted as a suspicious region is not explicitly explained by Nelson et al or Essenpreis et al. However, Alfano et al illustrate a shadow image in which the abnormalities are depicted in figures 3(a) to 3(d) and explain the depicted calcifications in column 7, lines 4-19. It is well-known in the art of mammography to identify the abnormalities corresponding to cancer, such as the calcifications identified by Alfano et al, in a shadow (transilluminated) image in order to determine the presence and extent of breast cancer present in a patient (Alfano et al: column 9, lines 23-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to display depicted abnormalities of a shadow image, as illustrated by Alfano et al, in the system of Nelson et al and Essenpreis et al because abnormalities that determine the presence of cancer would be viewable by a user.

v. A positioner for positioning the light source relative to the host medium such that the light source illuminate the host medium at the plurality of different positions, wherein the positioner initially positions the light source at a plurality of different positions that cover a broad portion of the host medium to facilitate generation of the shadow image and wherein the positioner subsequently positions the light source proximate that portion

of the host medium that includes the suspicious region following generation of the shadow image to facilitate characterization of the abnormality is illustrated by Nelson et al in figure 5. Nelson et al illustrate two sets of sources and detectors being able to scan the host medium in two directions, corresponding to the dotted arrows. The positioner positions the emitters and detectors to initially scan the entire host medium, corresponding to the breast, in order to generate a shadow image as illustrated by Alfano et al in figures 3(a) to 3(d). Ning explicitly explains performing a detailed interrogation (as performed by Essenpreis et al) of specific regions within a lesion, such as a microcalcification detected by Alfano et al, to enable more accurate characterization of the breast lesion in column 6, lines 3-9. In order to perform the detailed interrogation as explained by Essenpreis et al, it is inherent that the positioner of Nelson et al would position the emitters and detectors to the region proximate to the portion of the host medium including the suspicious region, so that the region can be imaged. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made for a positioner to position a light source relative to the host medium to initially cover a broad portion of the host medium and subsequently cover the portion of the host medium including the suspicious region, as suggested by Ning, in the system of Nelson et al, Essenpreis et al, and Alfano et al because the suspicious region will be more accurately characterized.

Referring to claim 19, the positioner for positioning the detector relative to the host medium, wherein the positioner maintains the light source and the detector in alignment while initially positioning the light source and detector and the positioner maintaining the light source

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and detector in an offset relation while subsequently positioning the light source and detector proximate that portion of the host medium that includes the suspicious region to facilitate the generation of the shadow image and the characterization of the abnormality is illustrated by Nelson et al in figures 5 and 17. The system of Nelson et al is capable of aligning of the source/detector combination in both an aligned and offset relation to illuminate a host medium.

Referring to claim 22, the host medium being a breast and the apparatus further comprising a pair of plates separated by a distance sufficient to receive the breast of a patient is illustrated by Nelson et al in figure 8a. The host medium is a breast (104) and the plates (102a and 102b) receive the breast.

Referring to claim 24, an opaque material filling a region defined by the plates that is unfilled by the breast is explained by Nelson et al in column 11, line 60 to column 12, line 15. The optical coupling material is explained to have a longer traveling path than the breast and therefore would be opaque.

Referring to claim 25, a background light source for illuminating any regions of separation between the opaque material and the breast is illustrated by Nelson et al in figure 8a by the light source 112. The light source illuminates the regions including the breast (104), optical coupling material (100), and any separation between the breast and the opaque material.

Referring to claim 27, the detector being a photomultiplier tube is explained by Nelson et al in column 12, lines 6-11.

Referring to claim 28, a diaphragm for selectively controlling an intensity of light that is presented to the detector is explained by Nelson et al in column 15, line 66 to column 16, line 9. Nelson et al explain that by collimating the beam, the cross-sectional area of the beam can be

reduced and thus the intensity of the beam controlled. Thus, the collimator acts as a diaphragm to adjust the intensity of light presented to the detector.

Referring to claim 31,

- i. A reference light source for illuminating the host medium with reference signals is illustrated by Nelson et al in figure 17. The reference light source could be any of the three light sources emitting light at  $\lambda_1$ ,  $\lambda_2$ , or  $\lambda_3$  wavelengths.
  - ii. A reference detector for detecting the reference signals following propagation through the host medium and the abnormality within the host medium is illustrated by Nelson et al in figure 17. Three detectors are illustrated that each detect light from a corresponding light source emitting a specific wavelength.
  - iii. A shutter for preventing further detection by the detector if the reference detector detects that an amplitude of the reference signals exceeds a predetermined threshold is explained by Nelson et al in column 6, lines 43-60. Nelson et al explain using optical shutters to analyze the radiation exiting the host medium. It is well-known in the art that shutter limit the amount of light entering a detector, such as those illustrated by Nelson et al in figure 17. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a shutter to prevent excess (above a threshold) light from entering a detector for better analysis of breast tissue.
11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Essenpreis et al, Alfano et al, and Ning, and further in view of Suni et al (U.S. Patent No. 5,590,166).

Referring to claim 20, the positioner comprises at least two X-Y linear motorized stages is not explicitly explained by Nelson et al or Essenpreis et al or Alfano et al or Ning. Though Nelson et al do illustrate linearly moving the source/detector combinations in figure 5, they do not explicitly explain using linear motorized stages. Suni et al explain using a linear motorized stage to vertically move a detection unit of a mammography system in column 2, lines 45-62. The linear motorized stages of Suni et al can be used to automatically adjust the linear position of the source/detector combinations used by Nelson et al. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use X-Y linear motorized stages, as suggested by Suni et al, to linearly move the two source/detector combinations of the mammography system of Nelson et al, Essenpreis et al, Alfano et al, and Ning.

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Essenpreis et al, Alfano et al, and Ning, and further in view of Bridges et al (U.S. Patent No. 6,061,589).

Referring to claim 21, the modulator comprises a frequency-swept network analyzer is not explicitly explained by Nelson et al or Essenpreis et al or Alfano et al or Ning. Though Essenpreis et al do explain modulating the source signal using a frequency generator (18 of figure 3) in column 5, lines 29-33, Essenpreis et al do not explicitly explain using a network analyzer to perform the modulation. Bridges et al do explain using a network analyzer to sweep the frequency of a signal in column 18, lines 30-38. It would have been an obvious matter of design choice to modify the frequency generator of the system of Nelson et al, Essenpreis et al, Alfano et al, and Ning by using a network analyzer to modulate the signal frequency, since the applicant has not disclosed that using a network analyzer solves any stated problem and it

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appears that any frequency generator would perform equally well as the claimed network analyzer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a frequency-swept network analyzer, as suggested by Bridges et al, to sweep the source signal across a range of frequencies in system of Nelson et al, Essenpreis et al, Alfano et al, and Ning.

13. Claims 23 and 26 are rejected under 35 U.S.C. 103(a) as being over Nelson et al, Essenpreis et al, Alfano et al, and Ning, and further in view of well-known prior art.

Referring to claim 23, an adjustable belt extending between the plates proximate the breast and the adjustable belt being tightened about the breast such that the breast fills a region defined by the pair of plates and the adjustable belt is not explicitly explained by Nelson et al or Essenpreis et al or Alfano et al or Ning. However, using an adjustable belt to tighten two plates around the breast is well-known in the art (official notice). By using an adjustable belt, the breast can be compressed further, resulting in better transillumination scanning of the breast tissue. Therefore, it would have been obvious to one of ordinary skill in the art the time the invention was made to use an adjustable belt to compress the breast so that the breast cancer can be more accurately detected in a patient in the system of Nelson et al, Essenpreis et al, Alfano et al, and Ning.

Referring to claim 26, a separation detector for measuring the distance by which two plates are separated is not explicitly explained by Nelson et al or Essenpreis et al or Alfano et al or Ning. However, using a distance sensor in order to determine the amount of separation between two plates is well-known in the art (official notice). By using such a sensor, a large separation (above a threshold) can be detected and corrected, resulting in a more uniform breast

scan. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to detect the separation distance between two plates compressing a breast in order to improve image quality and thereby improve breast cancer detection in a patient in the system of Nelson et al, Essenpreis et al, Alfano et al, and Ning.

14. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Essenpreis et al, Alfano et al, and Ning, and further in view of Franceschini et al (Franceschini, M.A. et al., Frequency-Domain Techniques Enhance Optical Mammography: Initial Clinical Results; Proc. Natl. Acad. Sci., USA, Vol. 94, pp. 6468-6473, June, 1997.).

Referring to claim 29, the light source comprising a first fiber optic pigtail infrared diode laser capable of emitting signals having a power level of between 100 milliwatts and 500 milliwatts and a wavelength of between 810 nanometers and 840 nanometers is not explicitly explained by Nelson et al or Essenpreis et al or Alfano et al or Ning. However, Franceschini et al explain using an 810 nm, 10 mW laser diode to frequency scan the breast in the abstract of this paper. Using an 100 mW to 500 mW source would have been an obvious matter of design choice in the, since the applicant only explains using these power levels on page 13, lines 25-27 of the specification and does not explain that such a power level solves any stated problem or is for any particular purpose. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an optical pigtail diode emitting light with a wavelength of between 810 nanometers and 840 nanometers and power between 100 milliwatts and 500 milliwatts, as suggested by Franceschini et al, in the system of Nelson et al, Essenpreis et al, Alfano et al, and Ning.

Referring to claim 30, the light source comprising a second fiber optic pigtail infrared diode laser capable of emitting signals having a power level of between 100 milliwatts and 500 milliwatts and a wavelength of between 670 nanometers and 700 nanometers is not explicitly explained by Nelson et al or Essenpreis et al or Alfano et al or Ning. However, Franceschini et al explain using a 690 nm, 10 mW laser diode to frequency scan the breast in the abstract of this paper. Using an 100 mW to 500 mW source would have been an obvious matter of design choice in the, since the applicant only explains using these power levels on page 13, lines 25-27 of the specification and does not explain that such a power level solves any stated problem or is for any particular purpose. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an optical pigtail diode emitting light with a wavelength of between 670 nanometers and 700 nanometers and power between 100 milliwatts and 500 milliwatts, as suggested by Franceschini et al, in the system of Nelson et al, Essenpreis et al, Alfano et al, and Ning.

15. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Essenpreis et al, Alfano et al, and Ning, and further in view of Wist et al (U.S. Patent No. 4,945,239).

Referring to claim 32, the light source comprising a fiber optic pigtail infrared diode laser operating in a continuous wave mode and capable of emitting signals having a wavelength of between 950 nanometers and 980 nanometers is not explicitly explained by Nelson et al or Essenpreis et al or Alfano et al or Ning. However, Wist et al do give an example of transilluminating breast tissue with light at 950 nm wavelength in column 2, lines 51-64. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention

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was made to use light at 950 nm to transilluminate the breast, as suggested by Wist et al, in the system of Nelson et al, Essenpreis et al, Alfano et al, and Ning because the lesions in the breast will be characterized more accurately.

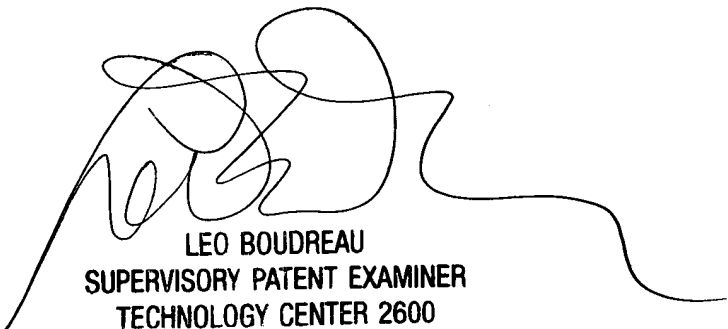
***Conclusion***

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hussein Akhavannik whose telephone number is (703)306-4049. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H. Boudreau can be reached on (703)305-4706. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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May 16, 2004



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